Nexium Control

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
N/0040	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/03/2024		PL	
II/0038	Submission of an updated RMP version 2.0 in order to update the list of safety concerns to meet the definition of important risk and missing information	06/07/2023	n/a		The MAH updated the list of safety concerns in the risk management plan removing risks that are well known and do not require further characterisation via additional

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	provided in GVP Module V Rev. 2 C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				pharmacovigilance activities, are without impact on the benefit-risk profile and are monitored via routine pharmacovigilance activities namely through signal detection and adverse reaction reporting and are minimised via routine risk minimisation activities namely product labelling.
IAIN/0039	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	24/04/2023		Annex II and PL	
N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/01/2022	17/02/2022	PL	
PSUSA/1269/ 202103	Periodic Safety Update EU Single assessment - esomeprazole	28/10/2021	n/a		PRAC Recommendation - maintenance
IB/0035	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	08/02/2021	17/02/2022	SmPC, Labelling and PL	
T/0033	Transfer of Marketing Authorisation	13/10/2020	10/11/2020	SmPC, Labelling and PL	
IB/0032	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	23/10/2020	n/a		

IB/0029/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	10/06/2020	10/11/2020	SmPC, Labelling and PL	
IB/0031/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	28/04/2020	n/a		
IB/0030/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary	31/03/2020	n/a		

	packaging, for non-sterile medicinal products B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation				
IA/0028	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	02/10/2019	n/a		
IA/0027	A.7 - Administrative change - Deletion of manufacturing sites	31/07/2019	n/a		
IA/0026	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	18/01/2019	n/a		
IB/0025/G	This was an application for a group of variations. B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter wit its corresponding test method as a result of a safety or quality issue B.II.d.1.g - Change in the specification parameters	08/01/2019	n/a		

	and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter wit its corresponding test method as a result of a safety or quality issue				
IB/0024	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	05/12/2018	05/12/2019	SmPC	
T/0023	Transfer of Marketing Authorisation	17/08/2018	28/09/2018	SmPC, Labelling and PL	
IB/0022/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP -	05/07/2018	n/a		

	Including batch control/testing B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
R/0021	Renewal of the marketing authorisation.	26/04/2018	25/06/2018	SmPC, Labelling and PL	
IAIN/0020	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	21/11/2017	n/a		
IA/0019	B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	08/09/2017	n/a		
IB/0018	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	29/08/2017	25/06/2018	SmPC and PL	

X/0016	Annex I_2.(d) Change or addition of a new pharmaceutical form	21/04/2017	15/06/2017	SmPC, Labelling and PL	
IAIN/0017	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/10/2016	15/06/2017	SmPC	
PSUSA/1269/ 201603	Periodic Safety Update EU Single assessment - esomeprazole	27/10/2016	n/a		PRAC Recommendation - maintenance
IB/0014	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/11/2015	26/05/2016	SmPC and PL	
IA/0013	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	23/10/2015	n/a		
IA/0011	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	13/08/2015	n/a		
IAIN/0010	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	23/07/2015	n/a		
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/07/2015	26/05/2016	Labelling and PL	

IAIN/0008	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	11/05/2015	26/05/2016	Annex II and PL	
IB/0007	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	08/01/2015	n/a		
IAIN/0006	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	04/12/2014	n/a		
IB/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/06/2014	27/05/2015	SmPC, Labelling and PL	
T/0004	Transfer of Marketing Authorisation from AstraZeneca AB to Pfizer Consumer Healthcare Ltd. Transfer of Marketing Authorisation	07/03/2014	21/03/2014	SmPC, Labelling and PL	
II/0001	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/01/2014	21/03/2014	SmPC and Labelling	The MAH summarised within this variation application efficacy results of esomeprazole 20 mg from the pivotal trials on the treatment of symptoms of reflux including heartburn and acid regurgitation over a 24 hour period during the first two weeks of usage extracted from the Clinical Study Reports. This data as per agreed update to 5.1 of the SmPC was considered to be valuable information to healthcare professionals and consumers on the clinical benefits to be expected from the once daily dosing of this medicine, during the first two weeks of treatment.

					In accordance the outer package text was amended introducing temporary the statement "new", the statements "lasts 24 hours", a placeholder for a website and an adaptation of the indication statement in line with the SmPC.
IAIN/0003/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	25/11/2013	n/a		
IAIN/0002/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	29/10/2013	21/03/2014	Annex II and PL	